UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,899	12/17/2003	Jeff D. Debad	4504-6	4043

23117 7590 03/14/2005

NIXON & VANDERHYE, PC
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON, VA 22201-4714

EXAMINER	
KOSSON, ROSANNE	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/736,899	DEBAD ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36 and 56-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-36 and 56-59* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13 and 57-59, drawn to a method for measuring a plurality of different organisms or a method for measuring two or more markers or one or more markers, comprising measuring markers of said organisms or said markers, classified in class 435, subclass 34.

II. Claims 14-24, drawn to a method for measuring a plurality of organisms, comprising measuring a streptococcal cell wall antigen and a viral marker, classified in class 435, subclass 5.

III. Claims 25-36, drawn to a kit for measuring a plurality of different organisms, classified in class 435, subclass 7.92.

IV. Claim 56, drawn to a method for extracting one or more markers from a matrix, classified in class 435, subclass 174.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of Group I and the method of Group II do not require each other for their practice; have separate utilities, such as detecting the presence of at least two types of organisms, any organisms, in a sample (Group I) versus detecting the

presence of a streptococcal cell wall antigen and a virus in an upper respiratory tract sample (Group II); are physically, chemically and biologically different from each other (because a reagent or step that detects multiple organisms may not detect streptococcal cell wall antigens or viruses); and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification. Therefore, these inventions are distinct.

Inventions I and III are related by virtue of the fact that the kit of Group III could be used in the method of Group I. Despite this relationship, these are distinct inventions because the kit of Group III is not required to practice the method of Group I, and the method of Group I may be performed with other reagents, depending on the type of organisms to be detected and the detection method desired. Antibody binding reagents may not be suitable or desired. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification. Therefore, these inventions are distinct.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of Group I and the method of Group IV do not require each other for their practice; have separate utilities, such as detecting the presence of at least two types of organisms, any organisms, in a sample (Group I) versus extracting one or more markers from a matrix (Group IV); are physically, chemically and biologically

different from each other (because Group I does not require a matrix or an extraction step, while Group II does not require more than one organism); and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification. Therefore, these inventions are distinct.

Inventions II and III are related by virtue of the fact that the kit of Group III could be used in the method of Group II. Despite this relationship, these are distinct inventions because the kit of Group III is not required to practice the method of Group II, and the method of Group II may be performed with other reagents, depending on the detection method desired. Antibody binding reagents may not be suitable or desired. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification. Therefore, these inventions are distinct.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of Group II and the method of Group IV do not require each other for their practice; have separate utilities, such as measuring a streptococcal cell wall antigen and a viral marker (Group II) versus extracting one or more markers from a matrix (Group IV); are physically, chemically and biologically different from each other (because Group II does not require a matrix or an extraction step, while Group IV does not require a streptococcal cell wall antigen); and are subject to separate

manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification. Therefore, these inventions are distinct.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the kit of Group III and the method of Group IV do not require each other for their practice; have separate utilities, such as detecting the presence of at least two types of organisms in a sample (Group III) versus extracting one or more markers from a matrix (Group IV); are physically, chemically and biologically different from each other (because Group III does not require a matrix or an extraction step or a viral marker, while Group IV does not require two different binding agents, a nitrite salt or a surfactant); and are subject to separate manufacture and sale from each other. These groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification. Therefore, these inventions are distinct.

Additionally, because the search for any one group is not required for the three other groups, an undue burden of both search and examination is created. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is clearly proper.

This application also contains claims directed to the following patentably distinct species of the claimed invention:

a) each of the second organisms recited in claim 5;

b) each of the markers recited in claim 16;

c) each of the viruses recited in claim 17;

d) each of the additional viral markers recited in claim 18, consonant with the election in claim 17;

e) each of the organism types recited in claim 30;

f) each of the second markers recited in claim 31;

g) each of the markers recited in claim 56;

h) each of the markers recited in claim 58;

i) each of the markers recited in claim 59, consonant with the election in claim 5.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species in each of groups a) – i) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 5, 14, 25, 56, 58 and 59 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

rk
2005-02-25

ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653